

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dme

|                  |          |
|------------------|----------|
| Display Date     | 12-21-99 |
| Publication Date | 12-22-99 |
| Certifier        | M. Bell  |

**Food and Drug Administration**

**21 CFR Part 177**

**[Docket No. 97F-0116]**

**Indirect Food Additives: Polymers**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

---

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 4-methylpentene-1 copolymers resulting from the copolymerization of 4-methylpentene-1 and 1-alkenes having from 12 to 18 carbon atoms for use in contact with food. This action is in response to a petition filed on behalf of Mitsui Petrochemical Industries, Ltd.

**DATES:** The regulation is effective (*insert date of publication in the Federal Register*); written objections and requests for a hearing by (*insert date 30 days after date of publication in the Federal Register*).

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Parvin M. Yasaei, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3023.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of April 1, 1997 (62 FR 15526), FDA announced that a food additive petition (FAP 7B4534) had been filed by Mitsui Petrochemical Industries, Ltd., c/o Keller and Heckman, 1001 G St. NW., suite 500 West,

Washington, DC 20001 . The petition proposed to amend the food additive regulations in §177.1520 *Olefin polymers* (21 CFR 177.1520) to provide for the safe use of 4-methylpentene-1 copolymers manufactured by the catalytic copolymerization of 4-methylpentene-1 with 1 -alkenes having from 12 to 18 carbon atoms in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that; (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and that therefore, (3) the regulations in § 177.1520 should be amended as set forth below in this document.

In accordance with §17 1.1 (h) (21 CFR 17 1.1 (h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 17 1.1 (h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before (insert date 30 days *after* date of publication in the **Federal Register**), file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the

regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### **List of Subjects in 21 CFR Part 177**

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

### **PART 177—INDIRECT FOOD ADDITIVES: POLYMERS**

1. The authority citation for 21 CFR part 177 continues to read as follows:

**Authority:** 21 U.S.C. 321,342, 348, 379e.

2. Section 177.1520 is amended by revising paragraphs (a)(3)(ii) and (c) in the table for items 3.3a and 3.3b under the heading “Olefin polymers” to read as follows:

#### **§ 177.1520      Olefin polymers.**

\*       \*       \*       \*       \*

(a) \* \* \*

(3) \* \* \*

(ii) 4-Methylpentene-1 and 1-alkenes having from 6 to 18 carbon atoms. Such olefin basic copolymers shall contain not less than 95 molar percent of polymer units derived from 4-methylpentene-1, except that copolymers manufactured with 1-alkenes having from 12 to 18 carbon atoms shall contain not less than 97 molar percent of polymer units derived from 4-methylpentene-1; or

\* \* \* \* \*



(c) \* \* \*

| Olefin polymers  | Density | Melting Point (MP) or softening point (SP) (Degrees Centigrade) | Maximum extractable fraction (expressed as percent by weight of the polymer in <i>N</i> -hexane at specified temperatures | Maximum soluble fraction (expressed as percent by weight of polymer) in <i>xylene</i> at specified temperatures |
|--|---------|---|---|---|
| <p>3.3a Olefin copolymers described in paragraph (a)(3)(ii) of this section and manufactured with 1-alkenes having from 6 to 10 carbon atoms.</p> <p>3.3b Olefin copolymers described in paragraph (a)(3)(ii) of this section, provided that such olefin polymers have a melt temperature of 220 °C to 250 °C (428 °F to 482 °F) as determined by the method described in paragraph (d)(8) of this section and minimum intrinsic viscosity of 1.0 as determined in paragraph (d)(9) of this section.</p> |         |   |   |   |

\* \* \* \* \*

Dated: 12/8/99  
December 8, 1999



L. Robert Lake  
Director  
Office of Policy, Planning, and  
Strategic Initiatives  
Center for Food Safety and Applied Nutrition

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

